IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 09/811,766	Confirmation No. 9295
Applicant(s)	: Appu Rao *et al.*	
Filed	: March 19, 2001	
TC/AU	: 1654	
Examiner	: Michael V. Meller	
Docket No.	: 000132850-0007	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION
(37 CFR 1.132)

The undersigned declares as follows:

(1) I am one of the applicants in the above-identified patent application. I am a Scientist working with the Central Food Technological Research Institute, Mysore (Karnataka), India from the year 1981. I was graduated from Mysore University, located at Mysore (Karnataka), India. I completed my Master's Degree from Mysore University, located at Mysore (Karnataka), India. Subsequently, I was graduated with a doctoral degree from Mysore University, located at Mysore (Karnataka), India. My specialization is in the areas of protein chemistry, oil seed processing, protein ligand interactions, physical bio chemistry, structure stability and enzymes.

(2) I have read and am familiar with the specification and claims of the instant application.

(3) I have read and am familiar with the Examiner's reasons for rejection of the claims of the present application and am also familiar with the prior art cited during the course of prosecution of the instant application.

(4) In his Office Action mailed April 1, 2005, the Examiner stated that *"[t]he table on page 10 of the declaration shows that in a comparison of a prior art process and that of the instant invention, that the prior art process yielded a degree of hydrolysis of 30-35% and that of the invention being at 35-45%. Fact is, the 35% overlaps both ranges making the results obtained by applicant as not unexpected and thus the rejection under 35 USC 103 remains proper."*

(5) In response to this statement in the Office Action, I acknowledge that the DH of the present invention (stated as being 35% - 45% in my prior Declaration) overlaps with the 30% - 35% of Option 4 of my prior Declaration. However, there is no overlap in the nitrogen content. When the DH, the nitrogen content, and the threshold reception of bitterness are considered in combination, there is no overlap of the product taken as a whole, and thus I submit that our results are unexpected.

(6) In further response to this statement in the Office Action, while acknowledging that the DH of the present invention overlaps with the 30% - 35% of Option 4, the higher end of the percentage must be given more weight based upon our test data. As set forth in the application as originally filed, Example 1 (page 10), the DH was 43%; in Example 2 (page 10), the DH was 39%; and in Example 3 (pages 10-11), the DH was 38%. Only in Example 4 (page 11) was the DH as low as 35%. Thus in the majority of instances our experiments demonstrated a DH *higher* than 35%. In fact, the majority of our experiments demonstrated a DH *equal to or higher* than 38%. Effectively, then, our results did not substantially overlap with the prior art ranges.

(7) Beyond the mechanical issue of DH percentages, I note also that protein content of the product of the present invention differs from that of the prior art in that it is higher than what is taught. This is important as the present invention is directed to *"A process for the preparation of protein hydrolysates ..."*

(8) "Protein hydrolysate" is defined as: "A sterile solution of amino acids and peptides prepared from a protein by acid or enzymatic hydrolysis and used intravenously for the maintenance of positive nitrogen balance in severe illness, after surgery of the alimentary tract, in the diets of infants allergic to milk, or as a high-protein dietary supplement." (Exhibit A)

(9) In addition, protein hydrolysate relates to a flavoring additive (21 USC Section 101.22) (Exhibit B).

(10) Beyond demonstrating imperceptible bitterness, the ideal protein hydrolysate obtained should have good protein content so that it can be used as a protein hydrolysate for fortification, dietary supplement as well as a flavoring agent. The present product has met all the above requirements.

(11) Specifically, our experiments also demonstrated a very high protein content of 65.63%-68.75% (10.5-11 x 6.25), determined by conversion from our original data as set forth in the attached Kjeldahl Chemistry, an extract from www.rosesci.com. (Exhibit C).

(12) The combination of this high protein content, the higher than average DH, the high nitrogen content, and the imperceptible bitterness embodied in the product of the present invention are results that are greater than expected given the teachings of the art. In cited USPN 6,007,851 to Schoenmaker *et al.*, the product is described as being "slightly bitter" (Example 1; col. 7, line 46). While the protein content is not defined in Example 1 of Schoenmaker *et al.*, it is defined in Example 8 (a similar, although not the same, composition; col. 9) as being 48% (line 42). One skilled in the art would presume by this teaching that to achieve a

higher protein content would result in a higher degree of bitterness, which is not the case here.

(13) In cited USPN 4,431,629 to Olsen, the product is described as having "no bitter taste" (Abstract, last line). Yet the product of Olsen has a DH that is in the range of 1% to 8% (col. 1, line 64 [percentages supplied in drawings]), with this percentage being kept intentionally low to *avoid* bitterness: "If DH is too high, bitter tasting products are produced ..." (col. 6, lines 42-43). One skilled in the art, looking to overcome the problems associated with producing protein hydrolysates from soy flour would consider the art as the Examiner has done but would reach the conclusion that increasing the DH above the highest taught (35%) would produce increased bitterness. I, together with my colleagues, have proven that this is certainly not the case, and that the *absence* of bitterness even with a high DH can be obtained provided that the process as described and claimed is followed.

(14) Particularly, the steps and parameters set forth and claimed in the specification were selected so as to produce a product which has the features of a high DH, a high nitrogen content, a high protein content, all with imperceptible bitterness. Specific selections include the particle size of the soy flour, the ratio of enzyme to substrate, the temperature, the pH and time interval controls through the end of enzymatic hydrolysis. In the present process defatted soy flour proteolytic enzyme is added to the aqueous slurry of defatted soy flour initially under a particular temperature and particular pH values. The hydrolysis of the soy flour slurry is allowed to proceed for a particular time period to form an intermediate product in the slurry. Subsequently, papain is added to the slurry without stopping the reaction under particular temperature and pH values and the further hydrolysis may be allowed to proceed for a particular time period.

The enzymes present in the reaction mixture are then deactivated to obtain the final product.

(15) The process of the present invention is a single stage or otherwise a single pot process and proteolytic enzyme is not deactivated at an intermediate stage. This approach includes adding the protease first (according to an optimum temperature/pH/time), then adding the papain (according to an optimum temperature/pH/time), and both enzymes are inactivated. The desired unique product results, all according to the steps defined and claimed in the present invention.

(16) I respectfully submit that the results we have achieved are unexpected and are contrary to the teachings of the prior art, demonstrating as they do a higher than expected DH coupled with a higher than expected nitrogen content while achieving a high protein content, all without bitterness, as one would expect given the teachings of the art.

I hereby declare that the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC Section 1001 and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Declarant/Inventor Name: Appu Rao Gopala Rao Appu Rao

Declarant/Inventor Signature: 

Date: 01 - 12 - 2005

protein hydrolysate

0.01 sec.

protein hydrolysate

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A sterile solution of amino acids and peptides prepared from a protein by acid or enzymatic hydrolysis and used intravenously for the maintenance of positive nitrogen balance in severe illness, after surgery of the alimentary tract, in the diets of infants allergic to milk, or as a high-protein dietary supplement.

Mentioned in

No references found

Medical browser

- protease inhibitor
- protection test
- protective laryngeal reflex
- proteid
- protein
- protein C
- protein channel
- **protein hydrolysate**
- protein metabolism
- protein S
- protein-bound iodine
- protein-bound iodine test
- protein-losing enteropathy
- proteinase
- proteinoid

Full browser

- Protein degradation
- Protein degradation
- Protein design
- Protein Design Labs, Inc.
- Protein Digestability Corrected Amino Acid Score
- Protein disulfide isomerase
- Protein domain
- Protein efficiency ratio
- Protein efficiency ratio
- Protein electrophoresis
- Protein electrophoresis test
- Protein Energy Malnutrition
- Protein engineering
- Protein engineering
- Protein expression
- Protein Expression, Purification and Crystallisation (Laboratory)
- Protein Extensible Markup Language
- Protein family
- Protein Family Database
- protein folding
- protein folding
- Protein Folding Group
- **protein hydrolysate**
- Protein Identification Resource
- Protein Information Resource
- Protein Information Resource
- Protein isoform
- Protein Kinase C (biochemistry)
- Protein kinase C alpha
- Protein kinase G
- Protein Kinase Inhibitors
- Protein kinases
- Protein Ligand
- Protein Ligand
- Protein Ligand
- Protein Ligand
- Protein ligands
- Protein Mannosyltransferase
- protein metabolism
- Protein methods
- Protein microarray
- protein molecule
- protein molecule

[**Code** of **Federal** Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR101.22]

[Page 72-77]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 101--FOOD LABELING--Table of Contents

Subpart B--Specific Food Labeling Requirements

Sec. 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservat

(a)(1) The term artificial flavor or artificial **flavoring** means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in Secs. 172.515(b) and 182.60 of this chapter except where these are derived from natural sources.

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(2) The term spice means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other **flavoring** principle has been removed. Spices include the spices

listed in Sec. 182.10 and part 184 of this chapter, such as the following:

Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric.

Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as ``spice and coloring'' unless declared by their common or usual name.

(3) The term natural flavor or natural **flavoring** means the essential oil, oleoresin, essence or extractive, **protein hydrolysate**, distillate, or any product of roasting, heating or enzymolysis, which contains the **flavoring** constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is **flavoring** rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in Secs. 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in Sec. 172.510 of this chapter.

(4) The term artificial color or artificial coloring means any ``color **additive**'' as defined in Sec. 70.3(f) of this chapter.

(5) The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial **flavoring**, artificial coloring, or chemical preservative shall be placed on the food or on its container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food. The specific artificial color used in a food shall be identified on the labeling when so required by regulation in part 74 of this chapter to assure safe conditions of use for the color **additive**.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial **flavoring**, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial **flavoring**, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k).

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity

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has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state ``All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration.'' Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., ``strawberry flavor'', ``banana flavor'', or ``natural strawberry flavor''. In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., ``natural and artificial strawberry flavor''. In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., ``artificial strawberry flavor''.

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as ``spice'', ``natural flavor'', or ``artificial flavor'', or any combination thereof, as the case may be.

(2) An incidental **additive** in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of Sec. 101.100(a)(3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name ``salt.''

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name ``monosodium glutamate.''

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(7) Because **protein** hydrolysates function in foods as both flavorings and flavor enhancers, no **protein hydrolysate** used in food for its effects on flavor may be declared simply as ``flavor,'' ``natural flavor,'' or ``**flavoring**.'' The ingredient shall be declared by its specific common or usual name as provided in Sec. 102.22 of this

chapter.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., ``vanilla'', in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in ``strawberry shortcake'', and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food,

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or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word ``natural'' and shall be immediately followed by the word ``flavored'' in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ``natural strawberry flavored shortcake,'' or ``strawberry flavored shortcake''.

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as ``artificially flavored.''

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words ``with other natural flavor'' in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) ``artificial'' or ``artificially flavored'', in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ``artificial vanilla'', ``artificially flavored strawberry'', or ``grape artificially flavored''.

(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a

part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food, e.g., ``artificially flavored vanilla and strawberry''.

(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor, e.g., ``artificially flavored fruit punch''.

(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it. The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor user shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of three years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized office or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health and Human

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Services. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable: Provided, That, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the

certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: Provided, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to Sec. 101.100 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., ``preservative'', ``to retard spoilage'', ``a mold inhibitor'', ``to help protect flavor'' or ``to promote color retention''.

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to Secs. 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

(1) A color **additive** or the lake of a color **additive** subject to certification under 721(c) of the act shall be declared by the name of the color **additive** listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the ``FD&C'' prefix or the term ``No.'' in the declaration, but the term ``Lake'' shall be included in the declaration of the lake of the certified color **additive** (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color **additive** following its common or usual

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name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as ``Artificial Color,'' ``Artificial Color Added,'' or ``Color Added'' (or by an equally informative term that makes clear that a color **additive** has been used in the food). Alternatively, such color additives may be declared as ``Colored with _____'' or ``_____ color'', the blank to be filled with the name of the color **additive** listed in the applicable regulation in part 73 of this chapter.

(3) When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for the color **additive**. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

[42 FR 14308, Mar. 15, 1977, as amended at 44 FR 3963, Jan. 19, 1979; 44 FR 37220, June 26, 1979; 54 FR 24891, June 12, 1989; 58 FR 2875, Jan. 6, 1993; 63 FR 14818, Mar. 27, 1998]

Food Labeling Guide

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collecting the distillate in a suitable trapping medium. ***With Foss Tecator's Kjeltec Systems, distillation takes less than five minutes.*** Today collection of ammonia is usually done by absorption into a solution of four percent boric acid. The ammonia is bound to the boric acid in the form of ammonium borate.

The Titration Step
Determination of the amount of nitrogen on the condensate flask can be accomplished by several methods. The most common is titration of the ammonia with a standard solution of one-tenth normal hydrochloric acid (0.1 H HCl) in the presence of mixed indicator. The mixed indicators (bromocresol green and methyl red) are available in the four percent boric acid solution.

Calculation
After all this chemistry it is now time to calculate the amount of nitrogen present in the sample. This calculation can either be performed as percent nitrogen or percent protein. For percent nitrogen:

$$\%\ N = \frac{14.01 \times (\text{ml titrant} - \text{ml blank}) - (\text{N of titrant}) \times 100}{\text{Sample Wt. (grams)} \times 1000}$$

It has been shown that protein is 16% nitrogen. (Wheat and dairy products are some exceptions.) By dividing 100 by 16, we get the conversion factor for nitrogen to protein of 6.25. Hence, the percent protein is calculated as follows:

$$\%\ \text{Protein} = 6.25 \times \%N$$

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